


Please amend the application as follows:

**IN THE CLAIMS**

In accordance with amendment practice pursuant to Rule 1.121(c)(1)(i), presented below is a "clean" copy of the rewritten claim. A "marked up" version of this claim is attached hereto as Exhibit 1 pursuant to Rule 1.121(c)(1)(ii).

Please amend the claims as follows:

 14. (Amended) A process for lowering serum cholesterol and triglyceride levels in a mammal comprising administering to the mammal an effective amount of the composition of claim 9.

**REMARKS**

Claim 14 has been amended for purposes of clarity and to depend from claim 9. Support for this amendment is found in the specification at, for example, page 4, lines 15-18 and in original claims 1, 9, and 14. See, *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

**Indefiniteness Rejection**

The Office Action purports to reject claims 9-14 under 35 USC §112, second paragraph. (Paper No. 5 at 2.) In making the rejection, the Examiner asserts that "[c]laim 14 is improperly dependent on claim 1, because claim 1 is cancelled" and that "the term comprising cited in claim 8 is inclusive and fails to exclude unrecited steps." (*Id.*)

Initially, we note that although the Office Action purports to reject claims 9-14, the Examiner only provides her reasoning for the rejection of claim 14. As is well settled, an Applicant is **not** required to guess at a rejection. As part of an Examiner's *prima facie* case, it is required that the Examiner explain with particularity why a claim is rejected. 35 USC § 132; see also, MPEP § 706.02(j) (8<sup>th</sup> Ed., Rev. 1, February 2003 p. 700-45). Here, the Examiner has failed to provide any reasoning to support the rejection of claims 9-13. Accordingly, the rejection of claims 9-13 must be withdrawn.

As to the comments regarding claim 8, we respond as follows. First, claim 8 was not rejected, thus it is unclear to us what relevance, if any, the Examiner's comments have with respect to the rejection of claims 9-14. Second, we are shocked that the PTO would issue a paper suggesting that the mere use of the term of art "comprising" would provoke a rejection under § 112, second paragraph. The term "comprising" is well defined by a myriad of case law that the PTO should know. See, e.g., *Genetech, Inc. v. Chiron Corp.*, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997); *Moleculon Research Corp. v. CBS, Inc.*, 229 USPQ 805, 812 (Fed. Cir. 1986); *In re Baxter*, 210 USPQ 795, 803 (CCPA 1981); and *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948); see also, MPEP 2111.03 (8<sup>th</sup> Ed., Rev. 1, February 2003 p. 2100-50). Accordingly, to the extent that claim 8 was "rejected" for the recitation of "comprising" it should be withdrawn immediately.

With respect to the rejection of claim 14, we note that it has been amended to depend from claim 9. Accordingly, the rejection has been rendered moot and should be withdrawn.

### **Obviousness Rejection**

Claims 9-14 were rejected under 35 USC §103(a) as being unpatentable over Higgins, III, U.S. Patent No. 6,147,236 ("Higgins '236") and Higashidate *et al.*, J. of Chromatography, 515: 295-303 (1990) ("Higashidate"). (Paper No. 5 at 2.)

For the reasons set forth below the rejection, respectfully is traversed.

Higgins '236 discloses a "method for the direct esterification of stanols and sterols with fatty acids to form stanol/sterol-esters." (Abstract.)

Higashidate discloses that "[m]ethyl esters of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in esterified fish oils were extracted by supercritical fluid extraction with carbon dioxide and directly introduced into a silica gel column coated with silver nitrate." (Abstract.)

In making the rejection, the Examiner asserted that the cited documents disclose "sterol esters and methyl esters of eicosapentaenoic acid [sic] (EPA) and docosahexaenoic acid (DHA), which embrace instantly, [sic] claimed invention." (Paper No. 5 at 2-3.) The Examiner acknowledged, however, that the "[p]resent claims differ from the reference in claiming a composition as in claim 9 for lowering the serum cholesterol and triglyceride levels whereas prior art US '236 [Higgins '236] teaches sterol esters with unsaturated fatty acids, for reducing serum cholesterol in a human examples given is same as one of the instantly claimed sterol ester, i.e. sterol with DHA, sitosterol docosahexaenoate and sitostanol docosahexaenoate...." (*Id.* at 3.)

To fill the acknowledged gap, the Examiner relied upon Higashidate as disclosing "DHA and EPA from fish oils and prevent diseases such as arteriosclerosis

and myocardial infarction by lowering the concentration of lipids and cholesterol in blood.” (*Id.* at 4.)

The Examiner then concluded that “it would have [been] obvious ... to prepare additional beneficial nutritional supplement using sterols with a pendent ester functionality which when hydrolyzed provides another cholesterol-lowering agent.” (*Id.*) The Examiner also asserted that because Higgins’ 236 discloses “such sterol esters” and Higashidate discloses “that fish oil contains omega-3 fatty acids (a class of PUFA) which includes docosahexaenoic acid (DHA) and eicosahexaenoic<sup>1</sup> acid (EPA), one would find ample motivation to prepare sterol esters with unsaturated fatty acids from active compounds present in fish oil ... or using unsaturated fatty acids from any other source lowering the cholesterol and triglyceride levels.” (*Id.*)

Initially, we note that when a rejection relies on an issued U.S. patent claiming benefit to an earlier filed application as a ***continuation-in-part***, it is incumbent upon the Examiner to make the necessary factual determinations as to whether the subject matter in the patent asserted is supported by the earlier filed application, *i.e.*, complies with the requirements of § 112, first paragraph. 35 USC § 120. Where, as here, the rejection fails to make these factual determinations, the rejection is insufficient as a matter of law and must be withdrawn. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993) (When a conclusion of obviousness is not based upon facts, it cannot stand.); *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970) (Obviousness ***must*** be based upon facts, “cold hard facts.”).

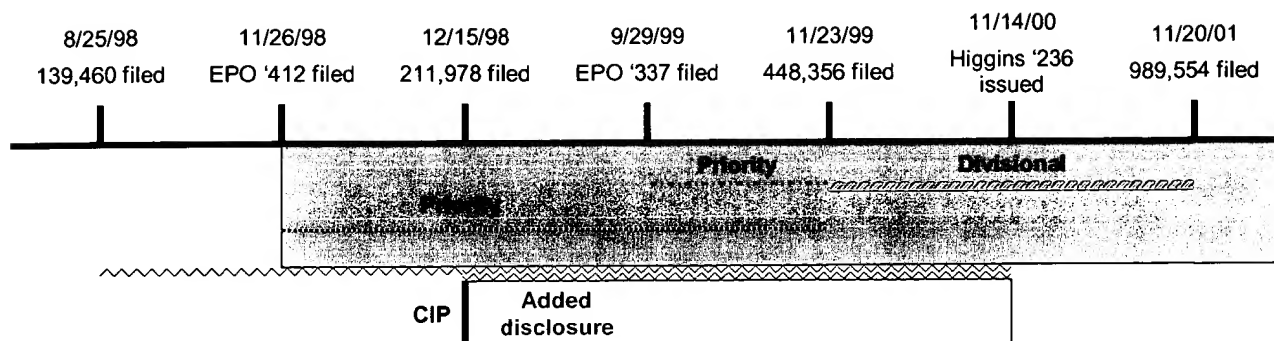
---

<sup>1</sup> This appears to be a typographical error. It is believed that the Examiner intended to write “eicosapentaenoic acid” and not “eicosahexaenoic acid” as indicated by the recitation of “EPA.”

Notwithstanding the infirmities noted above, and although it is not our burden, we demonstrate below that the Examiner is **not** entitled to rely on the August 25, 1998 filing date of Higgins, III, U.S. Patent No. 5,892,068 ("Higgins '068") in the present rejection because the subject matter relied upon in the rejection was not described or enabled in 09/139,460 ("460 application").

The present application is a divisional of USSN 09/448,356, filed November 23, 1999, which claims priority under 35 USC § 119 to EPO 98122412.4 ("EPO '412"), filed November 26, 1998 (Exhibit 2), and to EPO 99119337.6, filed September 29, 1999. The subject matter of claims 9-14 is fully supported and enabled by the disclosure of EPO '412 and is therefore entitled to benefit of its November 26, 1998 filing date. *Transco Products, Inc. v. Performance Contracting Inc.*, 32 USPQ2d 1077 (Fed. Cir. 1994). And, the Examiner has not – indeed, cannot – make a finding of fact that claims 9-14 are not entitled to benefit of EPO '412.

Higgins '236 has a filing date of December 15, 1998. Higgins '236 is a **continuation-in-part** of the '460 application, filed August 25, 1998, which matured into Higgins '068, which issued April 6, 1999. As is well settled, an application which is a C-I-P of an earlier application may claim priority to the earlier application only for the subject matter fully disclosed and enabled in the earlier application. *Transco Products* at 1082 n. 6; see *also*, MPEP § 2133.01 (8<sup>th</sup> Ed., Rev. 1, February 2003 p. 2100-76). Any newly added subject matter can only claim priority back to the filing date of the later application. For the Examiner's convenience, a timeline for the respective priority dates is set forth below.



The subject matter relied on by the Examiner to make the rejection is not disclosed in Higgins '068. A comparison of the two patents demonstrates that the vast majority of the DETAILED DESCRIPTION OF THE INVENTION, including the disclosure relied upon by the Examiner to make the rejection, was not present in the earlier application and was, therefore, new to Higgins '236. Attached is a computer comparison of the text of the two patents.<sup>2</sup> (Exhibit 3.) In this comparison, the Higgins '068 patent is used as the base and the notations indicate the differences found in Higgins '236. Blue double underline indicates additions to, and ~~red strike-through~~ indicates deletions from Higgins '068. Also attached is a copy of the printed version of Higgins '236 in which the added material is highlighted.<sup>3</sup> (Exhibit 4.) A review of the added material conclusively demonstrates that a large portion of the DETAILED DESCRIPTION OF THE INVENTION, including the very subject matter relied upon by the Examiner to make the present rejection, was new to Higgins '236, as were Examples 6-9.

<sup>2</sup> The text of the two patents was taken from the USPTO website. (See, <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=5,892,068.WKU.&OS=PN/5,892,068&RS=PN/5,892,068>, and <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=6,147,236.WKU.&OS=PN/6,147,236&RS=PN/6,147,236>.)

Specifically, the rejection relies on “lines 9-67, col. 2; cols. 3 and 4; lines 1-20, col. 5 in [Higgins] ‘236.” (Paper No. 5 at 3.) This amounts to the entire disclosure in Higgins ‘236 from the beginning of the DETAILED DESCRIPTION OF THE INVENTION (at column 2, line 9) to column 5, line 20. In addition, the rejection points to two structures in Higgins ‘236 at column 5, lines 13 and 14. (Paper No. 5 at 3.)

The disclosure in Higgins ‘068, however, contains **none** of the structures or compounds discussed by the Examiner in making the rejection. Accordingly, the Examiner’s apparent reliance upon the August 25, 1998, filing date of Higgins ‘068 cannot stand. The subject matter the Examiner relied upon to make the rejection has a filing date of **December 15, 1998**. Based on these facts, the following table lists the appropriate benefit dates that should be accorded the present application and the subject matter in Higgins ‘236 patent relied upon by the Examiner under the relevant<sup>4</sup> sections of the statute:

	CLAIMED INVENTION	HIGGINS ‘236
<b>102(a)</b>	November 26, 1998	November 11, 2000
<b>102(b)</b>	November 23, 1998	November 11, 2000
<b>102(e)</b>	November 26, 1998	December 15, 1998

Accordingly, the subject matter relied upon by the Examiner is not prior art to claims 9-14, and cannot be relied upon by the Examiner in making a § 103 rejection. Without Higgins ‘236, the primary document relied upon by the Examiner has been removed, which creates a significant factual gap that the Examiner has not

---

<sup>3</sup> Apparent corrections of typographical errors, other minor changes, and differences in the claims, which are immaterial to this discussion, have not been highlighted.

demonstrated can be filled by Higashidate. Accordingly, for this reason also, the rejection should be withdrawn.

For the reasons set forth above, entry of the amendment, withdrawal of the rejection, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 13, 2003.

  
Stephen J. Brown, Reg. No. 43,519

Respectfully submitted,

By: 

Stephen J. Brown  
Registration No. 43,519  
BRYAN CAVE LLP  
245 Park Avenue  
New York, NY 10167-0034  
Phone: (212) 692-1800  
Fax: (212) 692-1900

---

<sup>4</sup> Sections 102(c), (d), (f), and (g) are not at issue here and are therefore not discussed.



In re Application of:

Serial No.:

For:

David Carl BURDICK et al.

09/989,554

PHYTOSTEROL AND/OR PHYTOSTANOL DERIVATIVES



**MARKED-UP VERSION OF THE AMENDED CLAIM**

14. (Amended) A process for lowering serum cholesterol and triglyceride levels in a mammal comprising administering to the mammal an effective amount of the composition of claim 9 [compound of claim 1 in combination with a pharmaceutically acceptable carrier].